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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,500	11/30/2001	Beth Anne Lange	KCC 4775 (K.C. No. 17,12	6529
321	7590	12/17/2003	EXAMINER	
SENNIGER POWERS LEAVITT AND ROEDEL			KIDWELL, MICHELE M	
ONE METROPOLITAN SQUARE			ART UNIT	
16TH FLOOR			PAPER NUMBER	
ST LOUIS, MO 63102			3761	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/998,500

Applicant(s)

LANGE ET AL.

Examiner

Michele Kidwell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 – 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckley et al. (US 5,281,186), and further in view of Allen (US 6,361,806).

With respect to claim 1, Buckley et al. (hereinafter "Buckley") discloses a breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by a woman, the breast pad having a front side which faces the breast and a back side which faces the clothing, said front side comprising a composition for improving breast and nipple skin care health as set forth in col. 3, lines 28 – 35 and figures 1 and 3.

The difference between Buckley and claim 1 is the provision that the front side comprises  $0.1\text{g/m}^2$  to about  $30\text{g/m}^2$  of a composition comprising omega-3 fatty acids.

Allen teaches a cream comprising an omega-3 fatty acid as set forth in col. 8, lines 23 – 26.

It would have been obvious to one of ordinary skill in the art to modify the breast pad of Buckley to provide the composition taught by Allen because the composition of Allen promotes improvement of the skin as set forth in col. 7, line 64 to col. 8, line 6.

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Additionally, it would have been obvious to one of ordinary skill of the art modify the amount of the composition used (i.e.  $0.1\text{g/m}^2$  to about  $30\text{ g/m}^2$ ) based on the size of the delivery vehicle (i.e. a large breast pad, a nipple pad, etc.) since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only a level of ordinary skill in the art.

Regarding claims 2 – 3, 21 – 22, 36 – 37, 59 and 66, Allen teaches the claimed weight percentage of the omega 3 fatty acid as set forth in col. 12, lines 1 – 4.

Regarding claims 4 – 5 and 18 – 19, Allen teaches flaxseed oil as set forth in col. 28, lines 29 – 35.

With reference to claims 6, 24 and 42, Allen teaches vitamin C as set forth in col. 10, lines 13 – 17.

Regarding claims 7 – 8, 25 – 26, 43 – 44, 61, 65 and 68, Allen teaches the claimed pH as set forth in col. 10, lines 31 – 33.

As to claims 9, 27 and 45, Allen teaches a composition comprising 40% – 60% of a solidifying agent as set forth in col. 13, line 45 to col. 14, line 11.

With reference to claims 10, 11, 28, 29, 46 and 47, Allen teaches a composition comprising 1% – 40% of a fatty alcohol in the form of a sterol as set forth in col. 13, line 45 to col. 14, line 11.

As to claims 12, 30 and 48, Allen teaches the composition further comprising an extracted botanical as set forth in col. 14, lines 61 – 65.

It would have been obvious to one of ordinary skill in the art to modify the amount of extracted botanical used in the composition in order to achieve the desired

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product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only a level of ordinary skill in the art.

Regarding claims 13, 31 and 49, Allen teaches a composition comprising .01% – 10% of an emollient as set forth in col. 12, lines 1 – 3.

As to claims 14, 32 and 50, Allen teaches a composition comprising a viscosity enhancer as set forth in col. 10, lines 2 – 7.

It would have been obvious to one of ordinary skill in the art to modify the amount of viscosity enhancer used in the composition in order to achieve the desired product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only a level of ordinary skill in the art.

Regarding claims 15, 33 and 51, Allen teaches a composition comprising a rheology enhancer as set forth in col. 15, lines 39 – 43.

It would have been obvious to one of ordinary skill in the art to modify the amount of rheology enhancer used in the composition in order to achieve the desired product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only a level of ordinary skill in the art.

Regarding claims 16, 34 and 52, Allen teaches a composition as a cream as set forth in col. 12, line 1.

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With respect to claim 17, see the rejection of claim 1. Additionally, Allen teaches the use of an omega-6 fatty acid as set forth in col. 8, lines 19 – 22.

Regarding claim 20, Allen teaches the use of sunflower oil as set forth in col. 13, lines 55 – 60.

As to claims 23, 41, 57, 64 and 71, Allen teaches the ratio of omega-3 fatty acids to omega-6 fatty acids in the composition to be between 1:2 to about 2:4 as set forth in col. 19, table A.

With respect to claim 35, see the rejection of claims 1 and 17. The examiner notes that linoleic acid, the omega-6 fatty acid disclosed by Allen, is considered an essential fatty acids.

With reference to claims 38 and 39, Allen teaches the claimed amount of essential fatty acids as set forth in col. 19, table A.

As to claim 40, Allen teaches the use of an omega-6 fatty acid as set forth in col. 19, table A.

With respect to claim 53, see the rejection of claims 1, 17 and 35. Additionally, Allen teaches a composition comprising from about 1% to about 15% of flaxseed oil as set forth in col. 13, lines 32 – 65.

As to claim 54, Allen teaches a composition comprising from about 1% to about 15% of flaxseed oil as set forth in col. 13, lines 32 – 65.

As to claim 55, Allen teaches a composition comprising from about 1% to about 15% of essential fatty acids as set forth in col. 13, lines 32 – 49.

With reference to claim 56, see the rejection of claims 1, 17, 35 and 53. Additionally, Allen teaches the composition including linoleic acid as set forth in col. 8, lines 19 – 22.

With reference to claim 58, see the rejection of claims 1, 17, 35 and 53. The examiner contends that the claimed method steps would have resulted from the use of the device recited in claims 1, 17, 35 and 53.

As to claims 60 and 67, Allen teaches the claimed oil as set forth in col. 13, lines 55 – 67.

With respect to claims 62, 63, 69 and 70, Allen teaches a composition further including omega-6 fatty acids (i.e., essential fatty acids) in the form of linoleic acid as set forth in col. 19, table A.

With reference to claim 65, see the rejection of claims 1, 17, 35 and 53. The examiner contends that the claimed method steps would have resulted from the use of the device recited in claims 1, 17, 35 and 53.

### ***Response to Arguments***

Applicant's arguments filed October 8, 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a composition that treats the outer layer of the skin, a composition that improves skin and nipple health during breast feeding or a composition that can be safely

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ingested by a suckling infant) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The applicant's arguments are directed toward limitations that have not have been recited in the claims. The claimed invention is directed to a breast pad including a composition comprising omega-3 fatty acids. Buckley discloses a breast pad that may be impregnated with any commercially available lotion (col. 3, lines 31 – 35) and Allen discloses a breast treatment composition that includes omega-3 fatty acids.

The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not



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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 703-305-2941. The examiner can normally be reached on Monday - Friday, 7:30am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
Michele Kidwell  
December 15, 2003

  
WEILUN LO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700